NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| NOVARTIS PHARMACEUTICALS CORP. *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC.,<br><br>Defendant. | **Hon. Dennis M. Cavanaugh**<br><br>**OPINION**<br><br>Civil Action No. 05-CV-1887 (DMC) |

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motions by Defendant Teva Pharmaceuticals ("Teva") to dismiss Plaintiffs Novartis Pharmaceuticals Corp., Novartis Pharma AG, and Novartis International Pharmaceutical Ltd.'s (collectively, "Novartis") willful infringement claim under Fed. R. Civ. P. 12(b)(6) and 12(c) and for summary judgment that asserted claims 9 and 14–19 of the '937 patent are invalid for obviousness under Fed. R. Civ. P. 56. Pursuant to Fed. R. Civ. P. 78, no oral argument was heard. After considering the submissions of the parties, and based upon the following, the Court finds that Teva's motions to dismiss and for summary judgment are **denied**.

## I. BACKGROUND[1]

This is a patent infringement case arising under the Hatch-Waxman Act, which governs

[1] The facts set-forth in this Opinion are taken from the parties' statements in their respective moving papers.

the approval of generic drugs by the U.S. Food and Drug Administration ("FDA"). Novartis is the owner of United States Patent No. 5,246,937 (the "'937 patent"). Pursuant to the Hatch-Waxman Act, Teva filed an abbreviated new drug application ("ANDA") on December 28, 2004, seeking FDA approval to commercially manufacture famciclovir tablets. Teva's ANDA included a certification stating that the '937 patent is invalid and would not be infringed by Teva's application. On February 22, 2005, Teva sent a notice letter pursuant to the requirements of the Hatch-Waxman Act explaining why Teva's proposed generic version of Novartis' tablets would not infringe upon any valid or enforceable claim of the '937 patent. In response, Novartis filed a complaint alleging that Teva was infringing on the '937 patent.

The FDA granted final approval of Teva's ANDA in August 2007. Soon thereafter, Novartis moved for a preliminary injunction restraining Teva from proceeding with its generic tablets. The Court denied Novartis' request on September 25, 2007, finding, *inter alia*, that Novartis had failed to meet its burden of showing a likelihood that it would succeed on the merits of its infringement claim. Thereafter, Teva began selling its generic tablets. The Federal Circuit affirmed the Court's preliminary injunction order without an opinion on June 9, 2008. Novartis filed an Amended Complaint on June 24, 2008.

Currently before the Court are Teva's motions to dismiss the claim for willful infringement under Fed. R. Civ. P. 12(b)(6) and 12(c), and for summary judgment that asserted claims 9 and 14–19 of the '937 patent are invalid for obviousness under Fed. R. Civ. P. 56.

## II. STANDARD OF REVIEW

### A. *Motion to Dismiss Under Rule 12(b)(6)*

In deciding a motion to dismiss pursuant to Rule 12(b)(6) , all allegations in the complaint must be taken as true and viewed in the light most favorable to the plaintiff. See Warth v. Seldin, 422 U.S. 490, 501 (1975); Trump Hotels & Casino Resorts, Inc., v. Mirage Resorts Inc., 140 F.3d 478, 483 (3d Cir. 1998). If, after viewing the allegations in the complaint in the light most favorable to the plaintiff, it appears beyond doubt that no relief could be granted "under any set of facts which could prove consistent with the allegations," a court shall dismiss a complaint for failure to state a claim. See Hishon v. King & Spalding, 467 U.S. 69, 73 (1984). In Bell Atl. Corp. v. Twombly, the Supreme Court clarified the Rule 12(b)(6) standard. See 127 S. Ct. 1955 (2007). Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim, which would entitle him to relief." Twombly, 127 S. Ct. at 1968 (citing Conley, 355 U.S. at 45–46). Instead, the Supreme Court instructed that "[f]actual allegations must be enough to raise a right to relief above the speculative level." Twombly, 127 S. Ct. at 1965.

### B. *Motion for Judgment on the Pleadings Under Rule 12(c)*

The standard applied to a Rule 12(c) motion for judgment on the pleadings is similar to that applied to a Rule 12(b)(6) motion to dismiss. Haynes v. Metropolitan Life Ins. Co., 94 Fed. App'x 956, 958 (3d Cir. 2004). Under Rule 12(b)(6), courts must accept as true all allegations in the complaint, viewed in the light most favorable to the plaintiff. See Gomez v. Toledo, 446

U.S. 635, 636 n.3 (1980); Robb v. Phila., 733 F.2d 274, 277 (3d Cir. 1984). If no relief could be granted under any set of facts that could prove consistent with the allegations in the complaint, the court may dismiss the complaint for failure to state a claim. See Hishon, at 73; Bartholomew v. Fischl, 782 F.2d 1148, 1152 (3d Cir. 1986).

C. *Summary Judgment*

Summary judgment is granted only if all probative materials of record, viewed with all inferences in favor of the non-moving party, demonstrate that no genuine issues of material fact exist and that the movant is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986). The moving party bears the burden of showing that no genuine issues of fact exist. See id. "The burden has two distinct components: an initial burden of production, which shifts to the nonmoving party if satisfied by the moving party; and an ultimate burden of persuasion, which always remains on the moving party." Id. The non-moving party "may not rest upon the mere allegations or denials of his pleading" to satisfy this burden, but must produce sufficient evidence to support a jury verdict in his favor. See Fed. R. Civ. P. 56(e); see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). "[U]nsupported allegations in [a] memorandum and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990). "In determining whether there are any issues of material fact, the Court must resolve all doubts as to the existence of a material fact against the moving party and draw all reasonable inferences—including issues of credibility—in favor of the nonmoving party." Newsome v. Admin. Office of the Courts of the State of N.J., 103 F. Supp.2d 807, 815 (D.N.J. 2000), aff'd,

51 Fed. App'x 76 (3d Cir. 2002) (citing Watts v. Univ. of Del., 622 F.2d 47, 50 (D.N.J. 1980)).

## III. DISCUSSION

### A. *Motion to Dismiss*

Because Novartis has properly pled a claim for willful infringement, Teva's motion to dismiss under Rules 12(b)(6) and 12(c) is denied. Claims for willful infringement must show "by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." See In re Seagate Tech., LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007). Upon meeting this requirement, the patentee must also show that this objectively-defined risk of infringement "was either known or so obvious that it should have been known to the accused infringer." Id.

Here, Teva argues that Novartis' willful infringement claim should be dismissed because Teva launched its product after the Court denied Novartis' request for a preliminary injunction. In Seagate, the Federal Circuit noted that where a patentee attempts to secure injunctive relief and fails, "it is likely that the infringement did not rise to the level of recklessness" required for a willful infringement claim. Id. at 1374. Citing this, Teva argues that the denial of Novartis' injunction request establishes that substantial questions exist with respect to the validity and enforceability of the '937 patent, and that, as a result, Novartis cannot show that it acted with "objective recklessness." See id. at 1371.

While recognizing the difficulty that Novartis will face in attempting to satisfy Seagate's "obvious recklessness" standard in light of the denied preliminary injunction, the Court nonetheless agrees with Novartis that Seagate did not create a *per se* rule of dismissal, and finds

that it may be possible for Novartis to show after discovery that Teva acted in reckless disregard of the "objectively high likelihood" that it was infringing on a valid patent. Accordingly, and construing the facts in the light most favorable to the Plaintiff, the Court finds that Teva's motion to dismiss the willful infringement claim is denied.

B. *Summary Judgment*

Because genuine issues of material fact exist that prevent the Court from finding the '937 patent invalid for obviousness, Teva's motion for summary judgment is denied. Teva argues that the '937 patent is invalid because it would have been obvious to one of ordinary skill in the art to modify the known prior art compound penciclovir and arrive at famciclovir by following the express teaching of the prior art. Patents may be invalid for obviousness where:

> [t]he differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a). Obviousness is a question of law to be determined according to a series of factual inquiries, including: (1) "the scope and content of the prior art"; (2) "differences between the prior art and the claims at issue"; (3) "the level of ordinary skill in the pertinent art"; and (4) "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc." See Graham v. John Deere Co., 86 S. Ct. 684, 694 (1966); KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1734 (2007).

In this case, the Court finds that genuine issues of fact exist with respect to the scope, content and teaching of the prior art, differences between the prior art and the '937 patent, and

secondary considerations such as the failures of others, unexpected properties and commercial success. Accordingly, because these factual disputes preclude a finding at the summary judgment stage that the '937 patent is invalid for obviousness, Teva's motion for summary judgment is denied.

## IV. CONCLUSION

For the reasons stated, the Court finds that Teva's motions to dismiss and for summary judgment are both **denied**. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: February 23, 2009
Orig.: Clerk
cc: All Counsel of Record
Hon. Mark Falk, U.S.M.J.
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